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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,602	09/29/2003	Carlos Schuler	0076.10	9993

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EXAMINER	
PATEL, NIHIR B	
ART UNIT	PAPER NUMBER
3772	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,602	SCHULER ET AL.	
	Examiner	Art Unit	
	Nihir Patel	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10.19.2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer has been approved.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims **22 and 23** rejected under 35 U.S.C. 103(a) as being unpatentable over Seidler (US 5,816,404).

5. **As to claims 22 and 23,** a support member **34 (see figure 7)**; a plurality of outer blades **140 and 142 (see figure 7)** extending downward from the support member; a member **30 (see figure 7)** extending downward from the support member with the member being surrounded by the outer blades **(see figure 7),** wherein a distal end of the member includes a plurality of inwardly directed and outwardly facing blades **141 and 143 (see figures 6 and 7)** but does not provide plurality of blades extending downward from the support member at an angle in the

range from about 50 to 80 degrees and having a width in the range from about 0.3 to about 2 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Seidler's invention by providing provide plurality of blades extending downward from the support member at an angle in the range from about 50 to 80 degrees and having a width in the range from about 0.3 to about 2 mm. Since it has been held that where the general conditions of the claims are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art ***In re Aller,* 105 USPQ 233.**

6. Claims **24-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Newell et al. (US 4,778,054) in view of Seidler (US 5,816,404).

7. **As to claims 24, 29 and 30,** Newell substantially teaches an apparatus that comprises a housing **1 (see column 2 lines 40-45)** that is adapted to receive a receptacle **8 (see column 2 lines 50-60)** having a cover **4 (see column 2 lines 40-50)** with an exterior surface and an interior surface covering the cavity containing the powder **(see column 2 lines 55-65)**, a hole forming device **17 (see figure 2)** disposed within the housing, wherein the hole forming device is adapted to form at least one inlet opening and an outlet opening in the cover **(see figures 1 and 2)**; an aerosolizing system that is adapted to extract the powder from the receptacle **8 (see column 3 lines 30-40)** by drawing air through the inlet opening, through the receptacle **(see column 3 lines 30-40)** and out the outlet opening **(see column 3 lines 30-40)**; wherein the hole forming device comprises a support member **(see figure 2)** having at least one outer blade **(see figure 2)** extending downward from the support member , and moving mechanism to move the support member relative to the receptacle to move the outer blade through the cover and cause a cut portion of the cover to be removed away from the cavity to form an inlet opening and to cut an

outlet with the inner blade **(see figures 1 and 2)**, Seidler discloses plurality of blades but does not disclose a blade extending downward from the support member having an angle from about 50 to 80 degrees. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Newell's invention by providing a blade extending downward from the support member at an angle in order to provide a wider opening of the receptacle so that the medicament can be released more easily, and the angle being in the range from about 50 to 80 degrees. Since it has been held that where the general conditions of the claims are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art ***In re Aller,* 105 USPQ 233.**

8. **As to claims 25, 26 and 31,** Newell substantially discloses the claimed invention, see rejection of claim 24 above, but does not disclose a hole forming device comprising plurality of outer blades and wherein the blades have a width in the range from about 0.3 to about 2 mm. Seidler teaches an apparatus that does provide plurality of blades **140 and 142 (see figure 7)**. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Newell's invention by providing plurality of blades so that the integrity of the product contained in the compartment will be maintained and the product will the be contacted at any time during opening of the compartment by tearing away of film seal. It has also been held that where the general conditions of the claims are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art ***In re Aller,* 105 USPQ 233.**

9. **As to claims 27 and 32,** Newell discloses an apparatus that further comprises a gas source that is configured to flow a gas stream through at least a portion of the tubular member to

draw gases through the inlet openings, through the cavity and through the tubular member **(see column 4 lines 66-68 and column 5 lines 1-10)**.

10. **As to claims 28 and 33,** Newell discloses an apparatus that further comprsies a mouthpiece wherein suction on the mouthpiece causes a gas stream to flow through at least a portion of the tubular member to draw gases through the inlet openings, through the cavity and through the tubular member **(see column 4 lines 66-68 and column 5 lines 1-10)**.

11. Claims **1-3 and 8-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Newell et al. (US 4,778,054)

12. **As to claim 1,** Newell teaches a method step of comprising providing a receptacle **7** having a cover with an exterior surface and an interior surface covering a cavity **(see figure 1)**; providing a cutting mechanism having at least one blade **(see figure 2)**; piercing the cover with the blade **(see column 3 lines 20-30)**; moving the blade through the cover to cut a portion of the cover and create an opening in the cover and thereby provide access into the cavity as the opening is created **(see column 3 lines 20-30).**

The claimed method step would have been obvious because they would have resulted from the use of the device by Newell.

13. **As to claim 2,** Newell teaches a method step of rotating the cutting mechanism after the piercing step to move the blade through the cover to provide an elongate opening **(see column 3 lines 20-30).**

The claimed method step would have been obvious because they would have resulted from the use of the device by Newell.

14. **As to claim 3,** Newell teaches a method step wherein the cut portion curls upon rotation of the cutting mechanism **(see figure 12b).**

The claimed method step would have been obvious because they would have resulted from the use of the device by Newell.

15. **As to claim 8,** Newell teaches a method wherein the cavity has an outer periphery and further comprising forming the opening near the outer periphery **(see figure 1)**

The claimed method step would have been obvious because they would have resulted from the use of the device by Newell.

16. **As to claim 9,** Newell teaches a method step wherein at least a portion of the outer periphery is curved, and further comprises rotating the cutting mechanism such that the opening is curved along the outer periphery **(see figure 2).**

The claimed method step would have been obvious because they would have resulted from the use of the device by Newell

17. **As to claim 10,** Newell teaches a method step wherein the cutting mechanism further includes a center cutting device, and further comprising forming a central opening in the cover with the center cutting device while forming the opening **(see figure 2; the tip 21 is considered to a center cutting deice).**

The claimed method step would have been obvious because they would have resulted from the use of the device by Newell.

18. Claims **4-7 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Newell et al. (US 4,778,054) in view of Seidler (US 5,816,404).

19. **As to claims 4 and 11,** Newell substantially discloses the invention as claimed, see rejection of claims 1, 3, 8 and 10 above, but does not disclose multiple blades. Seidler teaches an apparatus that does provide multiple blades **(see figures 6 and 7)**. Therefore it would have been obvious at the time the invention was made to modify Newell's device by providing multiple blades as taught by Seidler so that the integrity of the product contained in the compartment will be maintained and the product will the be contacted at any time during opening of the compartment by tearing away of film seal.

20. **As to claim 5,** Newell substantially discloses the invention as claimed, see rejection of claim 1 above, but does not disclose three blades rotating the cutting mechanism through an angle in the range from about 70 to about 115 degrees. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Newell's invention by providing three blades rotating the cutting mechanism through an angle in the range from about 70 to about 115 degrees, since it has been held that where the general conditions of the claims are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art ***In re Aller,* 105 USPQ 233.**

20. **As to claims 6 and 7,** Newell substantially discloses the invention as claimed, see rejection of claim 1 above, but does not disclose multiple blades angled from the support member from about 50 to 80 degrees. Seidler teaches an apparatus that does provide multiple blades **(see figures 6 and 7)** but does not disclose the blades being angled in a forward direction relative to the support member from about 50 to 80 degrees. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Newell's invention by providing a blade extending downward from the support member at an

angle in order to provide a wider opening of the receptacle so that the medicament can be released more easily, and the angle being in the range from about 50 to 80 degrees. Since it has been held that where the general conditions of the claims are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art ***In re Aller,* 105 USPQ 233.**

21. Claims **12-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Newell et al. (US 4,778,054) in view of Seidler (US 5,816,404).

22. **As to claims 12, 16, 17, 20 and 21,** Newell substantially discloses a method step of providing a receptacle **8** having a cover with an exterior surface and an interior surface **(see figure 1)** covering a cavity that contains a powder **(column 2 lines 55-60)** and drawing air though the outer opening , through the cavity and out the inner opening to extract the powder from the receptacle and to aerosolize the powder **(see column 3 lines 30-40);** rotating the body to form an opening in the cover but does not disclose piercing the cover with the outer blades and the inner blades; moving the outer blades through the cover to cut a portion of the cover and to create an outer opening in the cover, with the cut portion being removed away from the cavity as the opening is created, and simultaneously moving the inner blades through the cover to cut an inner opening in the cover. Seidler discloses a method step of providing a cutting mechanism having at least one outer blade **140 and 142** and a plurality of inner blades **141 and 143**; piercing the cover with the outer blades and the inner blades; moving the outer blades through the cover to cut a portion of the cover and to create an outer opening in the cover, with the cut portion being removed away from the cavity as the opening is created, and simultaneously moving the inner blades through the cover to cut an inner opening in the cover **(see column 4 lines 59-67).**

Therefore it would have been obvious to modify Newell's device by providing a cutting mechanism having at least one outer blade **140 and 142** and a plurality of inner blades **141 and 143**; piercing the cover with the outer blades and the inner blades; moving the outer blades through the cover to cut a portion of the cover and to create an outer opening in the cover, with the cut portion being removed away from the cavity as the opening is created, and simultaneously moving the inner blades through the cover to cut an inner opening in the cover as taught by Seidler in order to prevent individual disposal of the cut film or even accidental ingestion thereof.

23. **As to claim 13,** Newell substantially discloses a method step wherein the cutting mechanism further comprises a support member **22 (se figure 2)** and further comprising maintaining the support member spaced apart from the cover when cutting the openings and when extracting the powder **(see column 3 lines 30-40)**

24. **As to claim 14,** Newell substantially discloses a method step wherein the outer openings has a width B and further comprises maintaining the support member spaced apart from the cover by a distance A, where A is greater than or equal to B **(see figures 10-13)**.

25. **As to claim 15,** Newell substantially discloses the claimed invention except for providing an opening wherein the width B is in the range from about 0.3 mm to about 2 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to providing an opening wherein the width B is in the range from about 0.3 mm to about 2 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art ***In re Aller,*** **105 USPQ 233.**

26. **As to claim 18,** Newell substantially discloses the invention as claimed, see rejection of claim 1 above, but does not disclose multiple blades angled from the support member from about 50 to 80 degrees. Seidler teaches an apparatus that does provide multiple blades **(see figures 6 and 7)** but does not disclose the blades being angled in a forward direction relative to the support member from about 50 to 80 degrees. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Newell's invention by providing a blade extending downward from the support member at an angle in order to provide a wider opening of the receptacle so that the medicament can be released more easily, and the angle being in the range from about 50 to 80 degrees. Since it has been held that where the general conditions of the claims are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art ***In re Aller,* 105 USPQ 233.**

27. **As to claim 19,** Newell substantially discloses an apparatus wherein the cavity has an outer periphery, and further comprising forming the outer opening near the outer periphery **(see figures 10-13).**

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 3772

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1/22/07